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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,070	10/15/2003	Henrik Hansen	10177-232	8917
20583	7590	12/21/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			PADGETT, MARIANNE L	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,070	HANSEN, HENRIK	
	Examiner	Art Unit	
	Marianne L. Padgett	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 20-37 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 34 and 36 is/are rejected.
- 7) ☒ Claim(s) 31, 35 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/2005 has been entered.

Note that nonelected claim 2 is dependent on a canceled claim.

2. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group of claim 30 is improper, because it contains species, which are not mutually exclusive, specifically it lists "polyurethanes" twice, but also terms such as polyesters or polyethers or silicones completely encompass other groups, such as polyvinyl esters or polyvinyl ethers or fluorosilicones, which are also listed.

Also, the examiner is uncertain of the meaning or intended scope of "alphaolefin", a term that she has not run across before and is not in her chemical dictionary. " α -[specific ligand] specific monomer" indicates position of the ligand in the molecule, but olefin is a generic category not a ligand and has the necessary ligand associated with it.

The acronym "EPDM" should be written out to appropriately define it, where the examiner also notes that on page 6 of the specification, line 33 recites "EPDM (ethylene-propylene-diene) rubbers", but there is no apparent source or meaning for the M in the acronym, so lacking an explanation, its use would appear to be misleading or inaccurate in association with ethylene-propylene-diene. Careful proofreading of the long list in this Markush group is recommended.

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 20-30, 34 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (6,355,058 B1), in view of Escallon et al (4,749,125) as applied/discuss in sections 5 & 3 of the 5/6/04 & 3/29/05 actions, and further in view of Leidner et al. (6,056,993) or Shikani et al. (5695458).

As noted in the 3/29/05 action, Pacetti et al. in view Escallon et al. do not teach the use of the claims solvents, tetrahydrofuran or chloroform or toluene or acetone or isooctane or trichloroethane, in their electrostatically sprayed polymeric solutions, however on further review of the prior art it has been found that Leidner et al. teaches electrostatically spraying polymer solutions, where the polymers may be silicone, high density polyethylene, polyurethane, polyester, polycarbonate,...or combinations thereof, with teachings on how to choose an organic solvent for a particular solution, wherefore the preferred silicone polymers, trichloroethane is the preferred solvent with halogenated alkanes generically taught as preferred, which is suggestive of chloroform, i.e. trichloromethane. Leidner et al. also optionally teach forming the composition such that it contains therapeutic ingredients, i.e. the equivalent of applicants' biologically active material. In Leidner et al., see the abstract; figure 1; col. 8, line 27-col. 9, line 56+; col. 10, lines 15-30 & 43-60, noting further only from her and polymer teachings including polyethylene glycol (PEG), poly (methylvinyl ether), polyacrylic acid, esters of poly (meth) acrylic acid, etc.; and col. 14, lines 42-67.

Leidner et al.'s technique is for actually making tubular prosthesis via deposition on mandrel, instead of merely coating them, however given that Pacetti et al. is coating stents, i.e. tubular prosthesis, via liquid electrostatic spraying that may include polymer binders of silicone or polycarbonate urethanes

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or polyethylene, etc., it would've been obvious for one of ordinary skill in the art to apply Leidner et al.'s teachings on solvents for electrospraying like materials for analogous purposes to the similar materials of Pacetti et al., particularly the use of halogenated alkanes, such as trichloroethane, when spraying silicones, to provide demonstrated effective solutions for the taught spraying technique, as taught in the combination of Pacetti and Escallon.

Alternately, Shikani et al. (458) teaches spraying polymer iodine coatings on medical products for disinfectant purposes, where successfully coated medical devices include catheters, tubes related to blood transfusions, needles and scalpel blades, all of which fit the criteria of being adapted for exposure to body tissue of the patient. Suggested polymers include polyethylene, silicone, polyvinyl chloride, polyethylene phthalate or polyesters, polypropylene, rubber, polyurethane, ethylene vinyl acetate, nylon, polycarbonate, cellulose esters, polystyrene, etc., where it is taught that polymers must be soluble in organic solvent solutions with useful organic solvents taught to include ethanol, aliphatic ketones (i.e. dimethyl ketone), tetrahydrofuran (THF) and chlorinated hydrocarbons. A specific exemplary composition to be sprayed was polyurethane in THF with iodine. In Shikani et al. (458), see figures 1-2; col. 2, lines 1-14, including incorporation by reference of Domb et al. (5,344,411) & Shikani et al. (5,437,656) with further discussion of coating medical devices; col. 3, lines 33-44 & 63-col. 4, line 2; col. 6, line 45-col. 7 lines 10, 25-38 & 49-col. 8, line 2; and col. 9, line 33-40.

Given the teachings of Shikani et al. (458) on effective solutions for spraying biologically affecting polymer coatings using organic solvents, such as THF or chlorinated hydrocarbons, it would have been obvious to one of ordinary skill in the art to employ taught affective solvents for such polymer solutions for the analogous liquid polymer compositions for electrostatic spraying taught in Pacetti et al., who is silent on the topic of claimed solvents, because effectiveness for overlapping polymers, such as polyurethanes, is demonstrated for sufficiently analogous purposes thus providing an expectation of the

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effectiveness of these taught and claimed solvents in the electrostatic spraying process of the combination of Pacetti and Escallon.

5. Claims 20-30, 32-34 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowlin et al. (2002/0081732 A1), noting that the filing date is October 18, 2001 with provisional applications 60/241,008 filed 10/18/2000 & 60/270,118 filed 2/22/2001, where (008) incorporates by reference SN 09/654,517 (abandoned, not IFW), SN 09/512,081 (abandoned, not IFW) and 09/386273 (now PN 6,592,623).

Bowlin et al. (2002/0081732 A1) teach electrospraying or electrospinning, where the substrate or target, which is being deposited on may be grounded and charge supplied to the solution in its source chamber, where compositions are inclusive of claimed polymers such as polylactic acid (PLA) or poly (ethylene-co-vinyl acetate) used with chloroform, with teachings on importance of and effective choice of solvent (abstract; figures 1-2 & 8; [0067]; [0070- 75, especially 73]; [0082-92]; [0102- 0110, especially 102-103, 106-107 & 110]), however for this reference to be prior art the provisional documents must supply appropriate support. In the (008) document, see figure 1; page 1-3; page 7 top; and claims 21-27, which supply the above relevant information, except for specific solvents, having only general teachings on the needs when selecting solvents. It is further noted that PN 6,592,623 incorporated by reference further illustrates relevant apparatus configurations in figures 2A, 2B & 7; col. 4-6 and in example 1 on col. 12-13 discusses the polymers PLA, polyglycolic acid (PGA) & copolymer of ethylene and vinyl acetate dissolves in solution with dichloromethane to be used for electrospinning. What information the two abandon applications supply, is not known at this time. Hence, while Bowlin et al. (732 A1) teach the claimed chloroform used in a claimed process, their support documents as available fall short of these, in that the chloroform is indicated to be used with the electrospinning, but no specific examples of solvent used with electrospraying is provided. However, it would've been obvious to one of ordinary skill in the art as the provisional (008) document teaches similar considerations in choice of solvent for both

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electrospraying and electrospinning, as well as teaching that electrospraying can be used in combination with electrospinning or by itself, to employ the taught polymer-chloroform compositions in the taught electrospraying as well as in the exemplified electrospinning, as the more general teachings suggest that such would have been applicable.

Specifically claimed parameters not set forth in the teachings of Bowlin et al. would have been expected to be determined by a routine experimentation, with variations expected due to particular choice of compositions including varying combinations of polymers, solvents and therapeutic agents, hence expected to be within or overlapping with claimed ranges.

6. Other art of interest for relevant compositions, i.e. polymers, solvent and/or biologically active material, use and/or spraying techniques, but which is not prior art includes: Herrmann; Weber et al.; Clerc et al.; Cheng; and Stenzel.

It was found that solvents such as chloroform have been commonly employed in the catalyzed polymerization reaction to produce copolymers or tripolymers containing styrene and isobutylene, particularly in association with the catalyst, but this does not provide motivation to use the claimed combination of chloroform with styrene-isobutylene-styrene polymeric material in the claimed electrostatic spray process.

7. Claims 31, 36 & 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

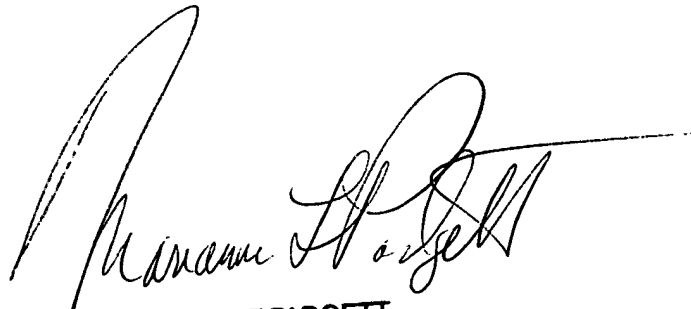
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP 12/7/2005



MARIANNE PADGETT
PRIMARY EXAMINER